Centaflox®

1. Generic Names

Moxifloxacin

Hydroxy propyl methyl cellulose

2. Composition

Moxifloxacin	0.5% w/v
Hydroxy propyl methyl cellulose	0.025% w/v

3. Dosage form and strength

Topical ophthalmic solution containing Moxifloxacin 0.5%(0.5mg/100ml).

4. Clinical particulars

4.1 Therapeutic indication

- In post cataract surgery
- Bacterial conjunctivitis

4.2 Posology and method of administration

Instil one drop in the affected eye 3 times a day for 5 to 7 days.

4.3 Contraindication

Moxifloxacin 0.5% ophthalmic solution is contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the components in this medication.

4.4 Special warnings and precautions for use

- Moxifloxacin 0.5% ophthalmic solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.
- In patients receiving systemically administered quinolones, including Moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose.
- If an allergic reaction to Moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment.

4.5 Drug interactions

Drug-drug interaction studies have not been conducted with Moxifloxacin 0.5% ophthalmic solution.

4.6 Use in special population

- Paediatric: The safety and effectiveness of Moxifloxacin 0.5% ophthalmic solution in infants below 1 year of age have not been established.
- Geriatric: No overall differences in safety and effectiveness have been observed between elderly and other adult patients.
- Liver impairment: No data found.
- Renal failure: No data found.
- Pregnancy and lactation: Since there are no adequate and well-controlled studies in pregnant women, Moxifloxacin 0.5% ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Centaflox eye drops is known.

4.8 Undesirable effects

In clinical trials the most frequently reported ocular adverse events were: decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperaemia, ocular pain, ocular pruritus, subconjunctival haemorrhage, and tearing. These events occurred in approximately 1-6% of patients.

4.9 Overdose

There is limited experience of overdose with Centaflox eye drops. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Moxifloxacin is a synthetic fluoroquinolone antibacterial agent active in vitro against a broad spectrum of Gram-positive and Gram-negative ocular pathogens, atypical microorganisms and anaerobes. The antibacterial action of Moxifloxacin results from inhibition of topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

HPMC drops are also known as 'artificial tears'. They are used to relieve eye dryness and soreness, particularly when the dryness is caused by a reduced flow of tears. They moisten, soothe and lubricate the surface of your eye, making it feel more comfortable.

5.2 Pharmacodynamic properties

Moxifloxacin is a quinolone/fluoroquinolone antibiotic. Moxifloxacin can be used to treat infections caused by the following bacteria: Aerobic Gram-positive microorganisms: *Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri, Streptococcus pneumoniae,* and *Streptococcus viridans* group. Aerobic Gram-negative microorganisms: *Acinetobacter lwoffii, Haemophilus influenzae,* and *Haemophilus parainfluenzae.* Other microorganisms: *Chlamydia trachomatis.*

Moxifloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Moxifloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria.

5.3 Pharmacokinetic properties

Moxifloxacin is readily absorbed from the gastrointestinal tract after oral doses with an absolute bioavailability of about 90%. It is widely distributed throughout the body tissues and is about 30 to 50% bound to plasma proteins. Moxifloxacin has an elimination half-life of about 12 hours, allowing once-daily dosing. It is metabolised mainly via sulfate and glucuronide conjugation, and is excreted in the urine and the faeces as unchanged drug and as metabolites, the sulfate conjugate primarily in the faeces and the glucuronide exclusively in the urine. Distribution into milk has been found in animals.

6. Nonclinical properties

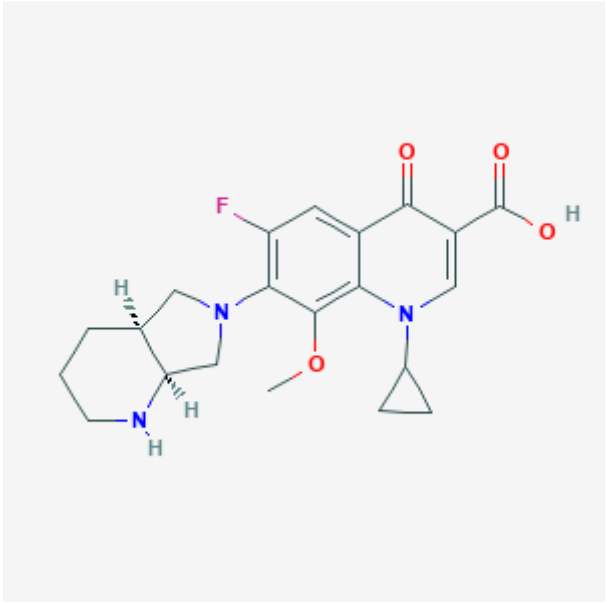
6.1 Animal Toxicology or Pharmacology

In vitro studies of fluoroquinolones with human or rabbit corneal epithelial cells or keratocytes suggest that moxifloxacin is similar in cytotoxicity potential to other drugs of this family. Specialized in vivo corneal wound-healing studies draw little distinction between moxifloxacin-treated eyes and those treated with other fluoroquinolones. Repeated-dose topical ocular studies in rabbits and monkeys, with high concentrations (up to 3%) of moxifloxacin and at treatment durations and regimens well in excess of label-prescribed use, demonstrated a high safety margin for ocular and extraocular tissues. Cornea, the tissue with highest exposure, was found to be unaffected by these high exposures, with slit-lamp biomicroscopy, corneal thickness measurement, intraocular pressure, and specular microscopy of the corneal endothelium (monkeys only), and histologic evaluation showing

no effects, as compared with controls. Moxifloxacin ophthalmic solution 0.5% affords superior efficacy and ocular tissue penetration, with a favourable safety profile.

7. Description

Moxifloxacin is a fluoroquinolone antibiotic with antibacterial activity. Its chemical name is 7-[(4*aS*,7*aS*)-1,2,3,4,4*a*,5,7,7*a*-octahydropyrrolo[3,4-b]pyridin-6-yl]-1-cyclopropyl-6-fluoro-8-methoxy-4-oxoquinoline-3-carboxylic acid. The empirical formula and molecular weight is $C_{21}H_{24}FN_3O_4$and 401.4 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

Centaflox eye drops is available in 5ml in plastic bottle.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by CENTAUR PHARMACEUTICALS PVT. LTD. and DCI Pharmaceuticals

11. Details of permission or license number with date

158(348)/MFG/DFDA/2010/15523 dated. 25.02.2010 for export.

12. Date of revision: January 2021